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Research Paper

Comparison of hemorrhoidectomy using harmonic scalpel and electrocautery: A randomized controlled trial*

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ABSTRACT

Aim: Hemorrhoids of grade III and IV require surgical management. Recurrence and postoperative pain have been reported to be associated with the type of surgical method. The aim of this study was to compare the hemorrhoidectomy using harmonic and electrocautery scalpel.

Materials and methods: The present study was a randomized clinical trial, enrolling patients with grade III and IV hemorrhoids. The patients were randomly divided into the two groups A and B, to receive hemorrhoidectomy using electrocautery and harmonic scalpel, respectively. Outcomes such as post-operative pain, bleeding and recurrence of hemorrhoids were recorded for all the patients. The data were analyzed statistically using SPSSv22.

Results: The demographic data was not significantly different among the two groups P < 0.05. The incidence of postoperative bleeding was greater in electrocautery group, however, non-significantly, p = 0.41. The recurrence of hemorrhoids was reported in 2 patients following 3 months in group A. At 6-month follow-up, 71.4% patients in group A and 28.6% in group B had recurrence of hemorrhoids. The pain was significantly lesser in group B p = 0.017.

Conclusion: Hemorrhoidectomy using harmonic scalpel is significant associated with reduced postoperative pain. Postoperative bleeding was also non-significantly lesser in this group.

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1. Introduction

Hemorrhoid disease is reported in approximately 3.3 million of ambulatory care cases, whereas, 10 million per year constitutes to the self-reported cases of hemorrhoids in the United States [1]. Hemorrhoids are characterized as the clusters of vascular and connective tissue along with smooth muscle in the anal canal at left lateral, right anterior, and right posterior positions [2]. External hemorrhoids are reported below the dentate line, covered with anoderm [3]. Internal hemorrhoids, below dentate line, are covered with columnar epithelium and are painless [4]. Internal hemorrhoids ae graded from I-IV based on their degree of prolapse and manifestation [5]. 40% of hemorrhoids are asymptomatic [4]. Grade I and II hemorrhoids are usually treatment via pharmacological approaches and the modification of lifestyle and diet. Surgical

intervention is required for grade III and IV hemorrhoids [6]. Hemorrhoidectomy is a most common and safest surgical method for the resection of hemorrhoids that is performed by the means of scissor, electrocautery, vascular-sealing devices or harmonic scalpel [5]. Postoperative pain following hemorrhoidectomy is associated with the type of excision device, incision, suturing of anal mucosa and surgical site infection [7]. Excision using harmonic scalpel is a newer technique and has been reported with better perioperative and postoperative outcomes [8]. It breaks the hydrogen bond and mediates the formation of coagulum vessels at hypothermic conditions and therefore, is associated with reduced damage to the surrounding tissue [9]. The consequential mucosal defect is left opened or closed based on the choice of the surgeon [10,11].

The aim of this study was to compare the outcomes of hemorrhoidectomy using harmonic and electrocautery scalpel.

2. Methods

This prospective double-blinded study was conducted at Nomadic Nursing Hospital from where patients with grade 3 and 4

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^{*} The study was approved by the Ethical Committee of Lorestan University of Medical Sciences (IR.LUMS.REC.1397.175).

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Table 1Frequency distribution of two in the two groups based on demographic data and postoperative outcomes characteristics (* Test: Kai Square).

Properties		Harmonic Scalpel hemorrhoidectomy		Electrocautery hemorrhoidectomy		Total	Percent	p-value
		Number	Percent	Number	Percent	•		
Sex	Male	52	47.7	57	52.3	109	100	0.249
	Female	28	54.9	23	45.1	51	100	
Age	40>	30	54.5	25	45.5	55	100	0.253
	40<	50	47.6	55	52.4	105	100	
Recurrent	+	12	66.7	6	33.3	18	100	0.41
	_	68	47.9	74	52.1	142	100	
Bleeding	+	10	66.7	5	33.3	15	100	0.282
	_	70	48.3	75	51.7	145	100	

symptomatic hemorrhoids, who were candidates for surgery were enrolled.

Sample method and sample size: All the patients meeting the criteria during our study period were included in this study and computer-based randomization was performed to divide patients into two equal groups. Group A underwent electrocautery hemorrhoidectomy (Ferguson's method) and group B underwent hemorrhoidectomy using harmonic scalpel.Inclusion criteria of the study included patients over 18 years of the age and having grade 3 and 4 drug resistant hemorrhoids. Patients with abscesses, anal fissures, recurrent hemorrhoids, diabetes, HIV infection and hemorrhagic disease excluded from the study. Written content was obtained from all the patients and details of the study were explained to them. Preoperative, a day before the surgery, patients in both the groups received glycerin enema. Before entering operation theater, patients were administered prophylactic antibiotics. Patients underwent spinal anesthesia and surgery, in both the cases, were performed in jackknife position. The two side of the buttocks were taped to the visualize anus and anoscope was inserted in the anal canal to visualize surgical field. The hemorrhoids were lifted from the stems using forceps and the resection was performed using monopolar electrocautery device in group A and harmonic scalpel using scissor configuration in group B. Following the excision of hemorrhoids, vicryl 3-0 sutures were placed. All the surgeries were performed by a single surgeon and a trained nurse was responsible to obtain postoperative parameters such as pain, recurrence of hemorrhoids, bleeding (follow-up period 3 and 6 months). The visual analogue scale (VAS) score was used to access postoperative pain ranging from 0 (no pain) to 10 (worst pain imaginable).

A questionnaire was designed for all the patients were patient's demographic data, surgical data and postoperative outcomes were noted.

The data were computerized and statistically analyzed using SPSS v22.Descriptive statistics were presented in tables and graphs. Independent and paired t-tests were used for comparison between groups. Non-parametric alternative tests were used if the data were not normal and the level of significance was set at 5%.The study was approved by the ethical committee of (XXX) University of Medical Sciences (XX).

3. Results

In this study, 80 patients underwent hemorrhoidectomy with electrocautery (group A) and harmonic scalpel (group B), respectively. The mean age of the patients in group A and B was 44.1 ± 8.4 and 44.0 ± 7.6 years, respectively. Other clinical and demographic characteristics of the groups are presented in Table 1.

In groups A and B, the frequency of male patients was 47.7% and 52.3%, respectively and that of female patients was 54.9% and 45.1%, respectively. There was no significant difference among

Table 2Comparison of mean pain rating in two methods of hemorrhoidectomy in the studied patients (* Test: Yuman Whitney).

Туре	Pain 24 h a	p-value			
	Total pain	Mean of pain	Median	Range	
Harmonic Scalpel hemorrhoidectomy	6987	87.34	0	(0-7)	0.017
Electrocautery hemorrhoidectomy	5893	73.66	0	(0-6)	

the two groups based on gender, p=0.249.ln group A, 54.5% patients were younger than 40 years of the age and 45.5% of those in group B. Whereas, in the group of patients over 40 years, 47.6% were in group A and 52.4% in group B. The age group difference was not statistically significant among the two groups, p=0.253.

In group A, 66.7% of the patients had intraoperative bleeding whereas, 33.3% in group B had intraoperative bleeding. The incidence of bleeding was not statistically significant, p = 0.41.

The recurrence of hemorrhoids was reported in 2 patients following 3 months in group A. At 6-month follow-up, 14 cases of recurrence were reported, 71.4% in group A and 28.6% in group B.

As can be seen in Table 2, the average pain rating in the group A was higher than group) 6.987 vs 5.893). The pain was significantly different among the two groups, p = 0.017.

4. Discussion

Conventional hemorrhoidectomy (open and closed) are considered as gold-standard for the treatment of III and IV grade hemorrhoids. However, it is associated prolonged recovery and morbidity [1].In the treatment of hemorrhoids, only 5–10% of symptomatic hemorrhoids require surgical treatment [12]. The common clinical signs leading to surgery include hemorrhoidal tissue prolapse that makes removal of hemorrhoids complicated [13].

Open surgery is commonly used in European, American, and Iranian countries, and most surgeons nowadays prefer to use this technique with more experience [14]. Hemorrhoidal tissue resection hemorrhage during surgery allows the surgeon to focus on resection of the tissue as well as appropriately ligating the hemorrhagic vessels that may not have temporary active hemorrhage [15]. The aim of this study was to compare the effects of harmonic and electrocautery hemorrhoidectomy. The results of our study indicated that the postoperative bleeding is similar in both the methods. 24 h postoperative pain scores are also significantly higher in electrocautery group.

Bulus, Tas [16] conducted a study enrolling 151 patients undergoing hemorrhoidectomy with harmonic or electrocautery cutting methods. The outcomes of the study reported that electrocautery was associated with prolonged hospitalization and

operating time and increased used of postoperative analgesia. Similarly, a prospective study by Alsayed Hamdy [17] reported that electrocautery method is likely to be associated with a greater incidence of anal stenosis, urine retention, prolonged operation time and increased blood loss and postoperative pain. Similar findings have been reported by Fayyaz [18] enrolled 60 patients undergoing hemorrhoidectomy with either method. The results of the study are in parallel with our studies indicating that harmonic scalpel is associated with relatively reduced postoperative pain and perioperative blood loss, hospitalization duration and recurrence of hemorrhoids.

In an Iranian study conducted in Kerman enrolling 53 patients undergoing harmonic or electrocautery hemorrhoidectomy, concluded that 24 h and 8-week postoperative pain and bleeding is significantly lesser harmonic scalpel group [19]. Our findings are in parallel with those from these studies. On the contrary, outcomes from the study by Dumlu, Gürer [20] indicated that the two methods might not differ in terms of postoperative pain measured by VAS, bleeding events, complications and the duration of hospitalization.

The outcomes of our study are limited to relatively lesser number of parameters. Preoperative morbidities, biochemical parameters, usage of drugs along with a number of perioperative and postoperative parameters can give better conclusion. Additionally, the percentage of stenosis also depends on the number of resected hemorrhoids and recurrence also depends on the surgical technique, which could have influenced the outcomes of our study.

5. Conclusion

24-h postoperative pain is significantly lesser with the use of harmonic scalpel for hemorrhoidectomy along with postoperative bleeding. This method might also influence other postoperative complications such as stenosis recurrence of hemorrhoids following 3 and 6 months of the follow-up period.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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No funding was secured for this study.

Author contribution

Dr. Mohammad Kazem shahmoradi: conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr. Jafar Mehri: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr. Hamid Reza Taheri: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

Guarantor

Mohammad Kazem Shahmoradi.

Registration of research studies

Name of the registry: Lorestan University of Medical Sciences.
Unique Identifying number or registration ID:
(IR.LUMS.REC.1397.175).

Hyperlink to the registration (must be publicly accessible): http://ethics.research.ac.ir/ProposalViewEn.php?id=48721.

Consent

Not applicable.

Disclosure

Approval of the research protocol: N/A.

Informed Consent: Informed consent was obtained from each participant.

Animal studies

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

Availability of data and material

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Conflict of interest statement

The authors deny any conflict of interest in any terms or by any means during the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijso.2020.10.006.

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